

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of Kimberly O. Cameron et al.

Examiner: Alton Nathaniel Pryor

Serial No.: 09/820,158

Filed: March 28, 2001

Art Unit: 1616

Title: Estrogen Agonists/Antagonists

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

37 C.F.R. §1.132 DECLARATION

I, David D. Thompson, a citizen of the United States of America residing at 37 Bittersweet Drive, Gales Ferry, CT declare as follows:

1. I, David D. Thompson was awarded the degree of Doctorate in Biological Anthropology from the University of Connecticut in 1978. In addition, I was an Assistant Professor at the University of Connecticut, Storrs from 1978- 1983, and the University of Connecticut School of Dental Medicine from 1983 - 1985

2. I, David D. Thompson, from 1990, and continuing to the present time, have been employed at the assignee of the instant application Serial No. 09/820,158. During this period, I have been responsible for drug discovery research and drug development research. Presently, I am Executive Director of the Specialty Medicines Unit with specific responsibilities for drug development in the area of osteoporosis and bone health

3. I am familiar with the instant application Serial No. 09/820,158 filed on March 28, 2001, and with the 35 U.S.C. §112, first paragraph rejection of the claims that is part of the final Office Action dated March 30, 2009.

4. I am aware of the clinical research results described hereinafter obtained from clinical trials carried out for the development of the compound lasofoxifene for use in preventing and treating osteoporosis. More specifically, I am aware of the clinical research results which show a reduction of risk of estrogen receptor positive breast cancer in patients on a 0.5 mg dose of lasofoxifene in the PEARL clinical trial.

Lasofloxifene, which is the species used in the instant prevention of breast cancer claims has undergone extensive clinical testing and has been previously submitted to the FDA for the prevention and treatment of osteoporosis and the treatment of vaginal atrophy. In the 5 year PEARL clinical study it was found that lasofloxifene at a 0.5 mg dose reduced the risk of ER+ (estrogen receptor positive) breast cancer by 67% through 3 years and by 81% through 5 years; reduced the risk of all breast cancer by 65% through 3 years and by 79% through 5 years; reduced the risk of ER+ invasive breast cancer by 73% through 3 years and by 85% through 5 years. Based upon these data one of ordinary skill in the art would recognize that these data show that lasofloxifene is useful in reducing the risk of breast cancer and thereby preventing breast cancer in humans.

Based upon the PEARL data it is apparent to one skilled in the art that lasofloxifene at a 0.5 mg dose reduces the risk of developing estrogen receptor positive breast cancer and therefore is useful in preventing breast cancer in those patients.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of said application Serial No. 09/820,158 or any patent issuing thereon.

Signed at New London, Connecticut, this 7th day of July 2009.

/David D. Thompson/

David D. Thompson